ORIGINAL

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA, Plaintiff, *ex rel.* JAMIE NOLL, Plaintiff-Relator, v. ELI LILLY AND COMPANY, Defendant.	)	***FILED IN CAMERA AND UNDER SEAL* pursuant to 31 U.S.C. § 3730 – FEDERAL FALSE CLAIMS ACT** CIVIL ACTION NO. 1 11-CV-0465

ORIGINAL COMPLAINT

1. On behalf of the United States of America pursuant to the *qui tam* provisions of the Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, plaintiff-relator JAMIE NOLL files this complaint against defendant **ELI LILLY and COMPANY** ("LILLY"). The damages sustained by United States because of LILLY's FCA violations is at least $275 Million.

SUMMARY OF LILLY'S ILLEGAL ACTIVITIES

2. This action concerns LILLY's fraudulent marketing activities relating to a prescription diabetes medication called Humalog 75/25 ("Mix 75/25"). Mix 75/25 consists of a mixture of 75% Insulin Lispro Protamine Suspension (ILPS) and 25% insulin lispro.

3. The Center for Disease Control has stated that, in 2007, diabetes imposes costs of $174 billion on the economy each year, in terms of treatment, medication, and lost productivity—of which $116 was for medical costs. In late 2010, UnitedHealth Group projected diabetes will cost the country $3.35 trillion over the next 10 years.

4. The diabetes treatment market was expected to top $15 billion in 2010, a 17% increase from the year before, according to statistics from IMS Health, Inc.

5. U.S.-based revenues during just the first six months of 2010 for an insulin medication called "Lantus" made by Sanofi-Aventis were $1.5 billion. Then Novo Nordisk's insulin medication generated the next most revenues. Last in line was LILLY's Humalog with sales of well less than $1 billion—more than ***50 percent less*** than Sanofi-Aventis. LILLY's revenues have substantially trailed leader Sanofi-Aventis for the past several years.

6. LILLY fell behind its competitors in the very lucrative U.S. insulin market—especially Sanofi-Aventis—because LILLY had no "true" basal insulin, *i.e.*, a one-injection-per-day/24-hour insulin with a relatively flat glucodyna/mic profile that can avoid hypoglycemia, which could compete with the insulins from competitors Sanofi-Aventis and Novo Nordisk.

7. So, several years ago, LILLY decided that to gain a larger share of the "basal insulin" market, its marketing activities must be based on a

head-to-head competition between LILLY's Mix 75/25 and Sanofi-Aventis's Lantus. LILLY knew it needed to represent in its marketing materials that Mix 75/25 has significant advantages over Lantus in patients with Type 2 diabetes.

8. To do so, LILLY has knowingly and willfully materially misrepresented that the ILPS component of Mix 75/25 was a "basal" insulin—a statement LILLY knew then, and continues to know, is materially false. LILLY has therefore made numerous material false and fraudulent statements and omissions in violation of the FCA.

9. LILLY materially manipulated significantly unfavorable trial data about Mix 75/25 to conceal key safety and tolerability data that was material to the determination whether Mix 75/25 was safer than competitors' insulins. By concealing this important data, LILLY ensured that:

(a) Mix 75/25 obtained new and continued formulary access to federal programs;

(b) Mix 75/25 continued to be prescribed by physicians on the basis of misleading information for patients whose medication is paid in whole or in part through a federal program; and

(c) LILLY evaded its duty to update the safety information on the FDA-approved label insert, which would have divulged the very adverse data LILLY wanted to conceal.

10. LILLY subsequently published its materially misleading trial data in widely read trade publications to falsely represent that Mix 75/25 has efficacy advantages over the insulins made and marketed by LILLY's competitors. LILLY's publications concealed key safety data showing Mix 75/25's actual effect on hypoglycemia and weight gain.

11. In addition, LILLY materially misrepresented in its marketing materials the results of a head-to-head data comparison of Mix 75/25 to Lantus by concealing Mix 75/25's substantially inferior safety profile compared to Lantus.

12. LILLY's marketing materials and the falsified reports in the trade publications are central to the prescription and payment decisions of and relied upon by: (a) physicians, (b) patients, (c) private insurers, and (d) carriers acting on behalf of the United States in connection federal programs that include, among others, Medicare Part D, Medicaid, TRICARE, and federal employee health programs.

13. Equally fraudulent has been LILLY's concealment of more recently collected testing data that once again confirmed the falsity of its marketing materials about Mix 75/25's comparative safety and tolerability profile vis-à-vis the insulins sold by competitors Sanofi-Aventis and Novo Nordisk.

14. LILLY's most recent SEC disclosures reveal that total Humalog sales, including Mix 75/25, in the United States for 2009 were ***$1.208 billion***, a 20 percent increase from the prior year. For the first six months of 2010, Humalog's U.S. sales were $609.5 million—a 5 percent increase from the same period in 2009. At least approximately 25 percent of LILLY's Humalog revenues are from sales of Mix 75/25, on information and belief.

15. According to the American Diabetes Association, 10.9 million people in the United States over the age of 65, or 26.9 percent of all people in this age group, have diabetes. That figure represents about 42 percent of the 25.8 million children and adults in the United States with diabetes, according to the ADA. Approximately 5-10 percent of all diabetes suffers have Type 1 Diabetes.

16. These figures prove that for FY 2009 alone, somewhere on the order of more than $400 million in Humalog sales, including Mix 75/25, were to individuals covered by Medicare Part D. And for Type 1 Diabetes during this same period, LILLY's Humalog revenues from Medicare Part D were between $20 million to $40 million.

17. From at least as early as on or about February 2006 to the present, Medicare Part D has sustained damages of at least approximately $250 million as a direct and proximate result of LILLY's material misrepresentations in connection with its sale of Mix 75/25, on information

and belief. During the same period, damages sustained by other federal programs as a result of LILLY's FCA violations exceed more than $25 million, on information and belief.

JURISDICTION AND VENUE

18. This action arises under the federal False Claims Act, as amended, 31 U.S.C. § 3729, *et seq*. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. §§ 3732(a) and 3732(b), and 28 U.S.C. §§ 1345 and 1367.

19. Court has personal jurisdiction over the defendants.

20. Venue is proper in this district under 31 U.S.C. § 3732(a). At least one defendant can be found, resides, or transacts business within this district, or at least one act proscribed by 31 U.S.C. § 3729 occurred within this district.

THE PARTIES

The Plaintiff-Relator

21. The plaintiff is JAMIE NOLL, acting in the capacity as relator for the United States pursuant to 31 U.S.C. § 3730(b) (the "Relator").

22. Relator has a Pharm. D. degree, *i.e.*, she is a Doctor of Pharmacy. She is a citizen of the United States and the State of Georgia.

23. From on or about November 15, 1994, through the present, Relator has been employed by LILLY. Relator was first hired as a sales

representative and, in or about 2001, rose to the level of district sales manager in neuroscience. In 2004, Relator entered a pharmacology doctorate program, as which point LILLY appointed her to a clinical research associate position. Prior to receiving her doctorate in 2007, LILLY promoted her to the position of clinical research scientist. In 2009, Relator was promoted to Senior Clinical Research Scientist.

The Defendant

24. LILLY is a publicly traded pharmaceutical manufacturer headquartered at LILLY Corporate Center, Indianapolis, Indiana 46285-0001. The defendant's agent for service in this judicial district is: National Registered Agents, Inc., 3675 Crestwood Parkway, Suite 350, Duluth, Georgia 30096.

25. LILLY is currently operating under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services (the "CIA"). The CIA requires LILLY to maintain comprehensive compliance programs governing its research, manufacturing, and sales and marketing of pharmaceuticals.

The Victim Programs Represented by the Relator

26. Medicare Part D, enacted via the Medicare Prescription Drug Improvement and Modernization Act of 2003, provides a prescription drug

benefit for seniors under the Medicare program. Insulin medication to treat diabetes is covered under Medicare Part D.

27. The Medicaid program provides medical benefits to qualifying low-income individuals who have no medical insurance or inadequate medical insurance. The Federal government establishes general guidelines for Medicaid benefits. However, specific eligibility requirements to receive Medicaid benefits, as well as the type and scope of services provided, are determined by the participating states. The Medicaid program in each state is financed with monies appropriated by the United States Congress and from the state itself.

28. The Veterans Administration, a part of the United States Department of Veterans Affairs, provides patient care and federal benefits to veterans and their dependents. The VA is funded with monies appropriated by the United States Congress.

29. TRICARE is a federally funded health care program that serves and covers active duty service members, National Guard and Reserve members, retirees, families and survivors worldwide.

30. Federal Employee Health Plans are available to federal employees. The U.S. government pays a portion of each participating employees' premium.

GROUNDS FOR THIS ACTION

LILLY Tries to Keep Up with the Competition

31. In or about 1998, LILLY first studied ILPS (insulin lispro protamine suspension) as an intermediate-acting insulin. This class of insulins has a longer time of action than short-acting insulins, but a shorter time of action than basal insulins (the 24-hour insulins).

32. Notably, intermediate-acting insulins have a peak of activity that is well known among pharmaceutical companies, the FDA, and prescribing physicians for putting patients at risk for hypoglycemia. The meteoric rise in market share for Sanofi-Aventis's Lantus was largely due to the fact that prescribing physicians understood that the drug was safer than intermediate-acting insulins because of its lack of a pronounced peak in activity.

33. LILLY's original purpose was to replace its NPH product (Neutral Protamine Hagedorn), also an intermediate-acting insulin used in mixtures containing lispro. The first mixture containing these insulins was Mix 75/25—which has been sold in the United States since approximately 2001.

34. By 2001, LILLY competitor Sanofi-Aventis began marketing an insulin called Lantus in the United States. Lantus was the first "true basal"—or 24-hour—insulin. Lantus is a clear, colorless solution designed to be injected once daily for the majority of patients with Type 2 diabetes

requiring insulin, to cover their insulin needs for 24 hours. Lantus quickly dominated the market as a "starter insulin," *i.e.*, an insulin for patients who never used insulin or "insulin naïve patients." Lantus currently is the top selling insulin sold in the world.

35. In 2005, LILLY competitor Novo Nordisk introduced a basal insulin marketed in the United States under the name Levemir (insulin detemir).

36. Notably, LILLY unsuccessfully attempted to bring ILPS to the U.S. basal-insulin market by demonstrating that ILPS is a true basal insulin. That is, 24 hour action by one injection daily, a flat PK/PD profile (*i.e.*, predicting an acceptable metabolic response to the drug), and low risk of hypoglycemia.

LILLY Uses Fraudulent Testing Practices and Marketing Activities to be Competitive

37. In or about 2005, LILLY still had no basal insulin it could market as a "24-hour" or "once daily" insulin.

38. By this time, Sanofi-Aventis began its domination of the basal insulin market in market share and revenues. Also, Novo Nordisk was also out-performing LILLY in new insulin starts and patient switches.

39. LILLY, desperate to gain market share—and, hence, revenues—initiated further studies of ILPS, which included Mix 75/25. In doing so,

LILLY sought to utilize a key characteristic of insulin: As the dose of the insulin is increased, its duration of action grows longer.

40. LILLY's new ILPS studies were led by Scott Jacober, D.O. and Liza Ilag, M.D.—but they did so in collaboration with *marketing* personnel, including Ron Hoven, Thane Wettig, and others. During its new studies, these LILLY employees knew that at normal doses in humans (around 0.4 – 0.5 units/kg), ILPS performed no differently than NPH—which is what Mix 75/25 was intended to replace.

41. At this point, LILLY—to wedge itself into the market—falsely reported in a published article a comparable rate of severe hypoglycemia for its ILPS compared to Novo Nordisk's Levemir (insulin detemir) in patients with Type 1 diabetes.

42. LILLY's Phase 3 studies also showed that a significantly greater number of patients required a second insulin injection to maintain the efficacy of Mix 75/25—in stark contrast to competitor Aventis's Lantus insulin—thus confirming that LILLY's Mix 75/25 was not a "true" basal insulin.

43. Notably, LILLY was already marketing ILPS in Spain, Italy, Japan, and Israel under the trade name Humabasal. But its test results did nothing to alter LILLY's claims about Humabasal overseas.

44. LILLY then published an article in the United States on the pharmacokinetics and pharmacodynamics of ILPS (the study had been designated "IOPC") compared to Levemir and Lantus. In the article's conclusion, LILLY materially misrepresented that the results of its recent study would support once-daily dosing of ILPS in Type 2 diabetes—a statement LILLY's studies had proved was false.

45. In the Fourth Quarter of Fiscal 2008, Relator—who had by then become a LILLY clinical research scientist (the "CRS")—reviewed the draft reports on two ILPS studies designated "IOOZ" and "IOOY." Serious deficiencies were documented. First, the IOOZ report did not discuss the fact that the test data showed that, ILPS caused more *nocturnal hypoglycemia.* Second—and even more dangerous—the drafts withheld the fact that ILPS, when used as LILLY did in its testing, caused *severe hypoglycemia* to a statistically significantly greater extent than the comparator Levemir.

46. LILLY suppressed the damaging information about hypoglycemia by revising a key definition in the original testing protocol so as to make statistically insignificant what was, under the definition established ***before*** any results were known, what were clearly statistically significant outcomes.

47. By rewriting this critical standard of measure ***after*** the data had been gathered and analyzed, LILLY successfully fabricated a favorable

outcome that was—in truth and in fact as LILLY well knew—***materially contradicted*** by the scientific facts that LILLY itself had gathered.

48. In 2009 and 2010, LILLY published reports of its three recent insulin studies IOPC, IOOZ, and IOOY in the United States—with each report knowingly concealing the materially adverse test results in order to justify the reports materially misleading conclusions. The reports appeared in: *Current Medical Research & Opinion*, Vol. 25, No. 11 2009, 2679-2687 (for IOPC); *Diabetic Medicine*, Issue 27, 563-569 (for IOOZ); and *Diabetic Medicine*, Issue 27, 181-188 (for IOOY).

49. In or about 2010, LILLY completed a study directly comparing Mix 75/25 to Lantus—the basal insulin by Sanofi-Aventis that physicians prescribed approximately 50 percent of the time more than LILLY's basal insulin—in patients with Type 2 Diabetes (study IOOV).

50. This direct comparison corroborated the unfavorable data from previous LILLY studies comparing Mix 75/25 to Lantus, in which—as before—there was a significantly greater incidence of hypoglycemia for Mix 75/25 compared to the competitor's insulin.

51. LILLY's study revealed even more damaging information. The difference in the incidence of hypoglycemia between Mix 75/25 and Lantus was especially magnified in patients 65 and older—*i.e.*, the Medicare Part D population.

52. But LILLY still has not disclosed this critical information in an updated safety profile for Mix 75/25—either to the FDA, as required, or to prescribing physicians.

53. And LILLY continues to market Mix 75/25 as a safe, efficacious, and comparable alternative to the insulins made by competitors Aventis and Novo Nordisk.

LILLY's False and Fraudulent Statements about Mix 75/25 Have Unlawfully Caused More Sales, Higher Rates of Reimbursement from Medicare Part D and Other Federal Programs, and More than $250 Million in Damages

54. By misrepresenting, concealing, and covering up its own test results proving that Mix 75/25 causes severe hypoglycemia—in its marketing materials and publications—LILLY has, for several years, not only misled physicians into prescribing Mix 75/25.

55. And LILLY's material false and fraudulent statements have also induced government programs, including Medicare Part D, not only to pay for the medication.

56. But by making these material false and fraudulent statements misrepresenting Mix 75/25's efficacy and important side effects, LILLY has fraudulently induced Medicare Part D, Medicaid, TRICARE, and other government-program formularies to give Mix 75/25 equal reimbursement status with Lantus and Levemir.

57. In other words, LILLY's material false and fraudulent statements about Mix 75/25 have (a) increased prescriptions thereby increasing potential revenues, and (b) induced federal programs to pay for the Mix 75/25 prescriptions likewise increasing revenues, but also (c) induced federal programs to pay for Mix 75/25 at a higher level of reimbursement—thus multiplying the damages sustained by the federal programs because of (a) and (b).

58. The proximate result of LILLY's material false and fraudulent test practices, misleading publications, and deceptive marketing disclosures has caused the United States to sustain damages exceeding more than $250 Million for Medicare Part D and at least an additional $25 million for all other federal programs, on information and belief.

COUNT I
(Violation of 31 U.S.C. § 3729(a)(1): Submission of a False or Fraudulent Claim for Payment)

59. Plaintiff-Relator JAMIE NOLL hereby realleges and incorporates by reference paragraphs 1 through 58 of this Complaint.

60. This is a claim for damages and civil money penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, against defendant **ELI LILLY and COMPANY** for knowingly presenting or causing to be presented false or fraudulent claims for payments from the United States, through Medicare

Part D, Medicaid, TRICARE, the Veterans Administration, and Federal Employee Health Plans, all in violation of 31 U.S.C. § 3729(a)(1).

61. These claims were false or fraudulent because the defendant induced the purchase of a product that was, based on its concealment of material information, not medically necessary or justified as required by law.

62. Defendant **ELI LILLY and COMPANY** presented or caused to be presented these claims for payment to the United States, knowing such claims were false or fraudulent.

63. By virtue of the false or fraudulent claims presented or caused to be presented by defendant **ELI LILLY and COMPANY**, the United States has suffered actual damages in an amount to be determined at trial, is entitled to recover three times the amount by which it was damaged, plus civil money penalties of not less than $5,000 and not more than $10,000 for each of the false or fraudulent claims presented or caused to be presented, plus interest, attorney's fees, and costs.

COUNT II
(Violation of 31 U.S.C. § 3729(a)(2): Creation or Use of a False or Fraudulent Statement to Obtain Payment)

64. Plaintiff-Relator JAMIE NOLL hereby realleges and incorporates by reference paragraphs 1 through 63 of this Complaint.

65. Defendant **ELI LILLY and COMPANY** knowingly made, used, or caused to be made or used, false or fraudulent statements and certifications to get a false or fraudulent claim allowed or paid by the United States, in violation of 31 U.S. C. § 3729(a)(2).

66. The United States has been damaged by the creation or use, or both, of false statements to obtain fraudulent payments or approval by defendant **ELI LILLY and COMPANY** in an amount to be proven at trial.

67. The United States has suffered actual damages and is entitled to recover three times the amount by which it was damaged, plus civil money penalties of not less than $5,000 and not more than $10,000 for each of the fraudulent claims presented or caused to be presented, plus interest, attorney's fees, and costs.

COUNT III
(Violation of 31 U.S.C. § 3729(a)(3): Conspiracy to Defraud By Getting a False or Fraudulent Claim Paid or Allowed)

68. Plaintiff-Relator JAMIE NOLL hereby realleges and incorporates by reference paragraphs 1 through 67 of this Complaint.

69. Defendant **ELI LILLY and COMPANY** and others known and unknown did combine, conspire, confederate, and agree, and reach an understanding and agreement, both express and implied, with each other and

with others, to defraud the United States by getting false or fraudulent claims paid or allowed, in violation of 31 U.S. C. § 3729(a)(3).

70. The United States has been damaged by the creation or use, or both, of false records to obtain fraudulent payments or approval by defendant **ELI LILLY and COMPANY** in an amount to be proven at trial.

71. The United States has suffered actual damages and is entitled to recover three times the amount by which it was damaged, plus civil money penalties of not less than $5,000 and not more than $10,000 for each of the fraudulent claims presented or caused to be presented, plus interest, attorney's fees, and costs.

PRAYER FOR RELIEF BY PLAINTIFF-RELATOR

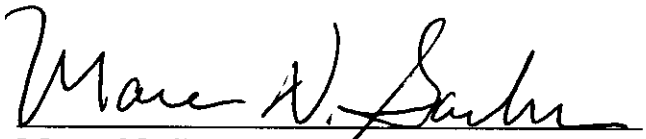
WHEREFORE, Plaintiff-Relator JAMIE NOLL respectfully prays that:

A. With respect to Counts I-III, judgment be entered in favor of Plaintiff-Relator JAMIE NOLL, on behalf of the United States and against defendant **ELI LILLY and COMPANY for all damages sustained by the** United States as provided by the False Claims Act, for civil money penalties of not less than $5,000 and not more than $10,000 for each of the false or fraudulent claims presented or caused and false or fraudulent records, statements, or certifications presented, plus interest, attorney's fees, and costs;

B. Such other and further relief and benefits be ordered as the cause of justice may require.

JURY DEMAND

PLAINTIFF DEMANDS A TRIAL BY A STRUCK JURY.



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